



ALZA Docket No. ARC-2300N2
J&J Docket No. ARO-7793

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Sonya Merrill et al.

Serial No. : 09/905,526

Art Unit: 1617

Filed : July 13, 2001

Examiner: Shahnam J. Sharareh

For : HYDROMORPHONE THERAPY

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January 12, 2004

(Date of Deposit)

Louis J. Capezzuto

(Name of applicant, assignee, or Registered Representative)

(Signature)

January 12, 2004

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

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information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☒ Please charge Deposit Account No. 10-0750/ARC-2300N2/ARO-7793/LJC the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request. Some copies of references are not provided because they were previously cited or submitted to the Office in prior applications:
USSN: 09/905,526, filed 09/22/97, (pending);
USSN: 09/224,188, filed 02/04/99;

USSN: 08/80935,223, filed 09/22/97 (Now Patent 5,914,131);
USSN: 08/611,294, filed 03/05/96 (Now Patent 5,702,725);
USSN: 08/271,593, filed 07/07/94 (Now Patent 5,529,787).

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.

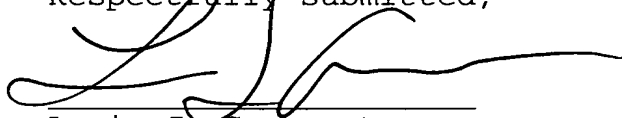
☒ The relevance of those listed references which are not in the English language is as follows: Reference French Patent No. 2,340,727 was cited as an "A" reference in the EPO Search Report. See English Abstract (attached).

☒ Attached is a copy of PCT Search Report from corresponding PCT application PCT/US95/07950, and a copy of the EPO Search Report from corresponding EPO Patent Application No. 99204122.8-2112 listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to
Deposit Account No. 10-0750/ARC-2300N2/ARO-7793/LJC. This form
is submitted in triplicate.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Louis J. Capezzuto', written over a horizontal line.

Louis J. Capezzuto
Reg. No. 37,107
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2218
DATED: January 12, 2004



SUBMISSION UNDER MPEP 609 D Page 1 of 1	<i>Application Number</i>	09/905,526
	<i>Filing Date</i>	July 31, 2001
	<i>First Named Inventor</i>	Sonya Merrill
	<i>Group Art Unit</i>	1617
	<i>Examiner Name</i>	Shahnam J. Sharareh
	<i>Attorney Docket Number</i>	ALZA: ARC-2300N2 J&J: ARO-7793

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No. ¹	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code ² (if known)	

FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No. ¹	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
			Office ³	Number ⁴	KindCode ⁵		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner 's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		PCT/US95/07950 SEARCH REPORT dated 07/07/1994	
		EPO NO. 99204122.8 SEARCH REPORT dated 10/31/2000	

Examiner Signature		Date Considered	
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STATEMENT BY APPLICANT**

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Sheet 1 of 2

Application Number	09/905,526
Filing Date	July 13, 2001
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Group Art Unit	1617
Examiner Name	Shahnam J. Sharareh
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U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		5,968,551		OSHLACK et al.	10/19/1999	
		5,681,585		OSHLACK et al.	10/28/1997	
		5,312,387		ROSSINI et al.	05/17/1994	
		5,273,760		OSHLACK et al.	12/28/1993	
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		4,160,020		AYER et al.	07/03/1979	
		4,126,684		ROBSON et al.	11/21/1978	
		4,088,864		THEEUWES et al.	05/09/1978	
		4,063,064		EGENBURGER et al.	12/13/1977	
		3,845,000		PASLEY	10/29/1974	
		3,598,123		ZAFFARONI	08/10/1971	
		3,598,122		ZAFFARONI	08/10/1971	
		3,546,876		FOKKER et al.	10/18/1968	
		3,541,006		BIXLER et al.	11/17/1970	
		3,541,005		STRATHMANN et al.	11/17/1970	
		3,276,586		ROSAEN	10/04/1966	
		3,173,876		ZOBRIST	03/16/1965	
		3,133,132		LOEB et al.	05/12/1964	
		2,799,241		WURSTER	07/16/1957	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵				
		EP	0 220 805	A2	Euroceltique SA	05/06/1987		
		EP	0 232 877	A2	Zetachron, Inc.	08/19/1987		
		FR	2 340 727		CIBA-GEIGY AG (With English Abstract)	09/09/1977		
		GB	2 196 848	A	Euroceltique SA	05/11/1988		

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**INFORMATION DISCLOSURE
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Sheet 2 of 2

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Encyclopedia of Pharmaceutical Technology, Swarbrick & Boylan Eds., 4:121-160, Marcel Dekker, Inc., 1991.	
		Goodman & Gilman's The Pharmacological Basis of Therapeutics, 8 th Ed., pp 485-518, Pergamon Press, 1990.	
		Handbook of Water Soluble Gums and Resins, Robert L. Davidson Editor, pp 18-1, 18-3, 19-1, 19-3, McGraw Hill Book Company, 1980.	
		Dale E. Wurster, "Air-Suspension Technique of Coating Drug Particles", J. Am. Pharm. Assoc, 48(8):451-454, August 1959.	
		Dale E. Wurster, "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", J. Am. Pharm. Assoc, 49(2):82-84, February 1960.	
		McGraw-Hill Dictionary of Scientific and Technical Terms, 3 rd Ed., pp. 620, 1228, 1243 and 1587	
		P. Grafton, "General principles for designing with plastics", Modern Plastics Encyclopedia, 46:62-70, 1969.	
		Perry's Chemical Engineers Handbook, 6 th Ed, pp 21-15, Table 21-6, McGraw Hill, 1984.	
		Remington's Pharmaceutical Sciences, 14 th Edition, Ch.86 "Powders", pp 1626-1648 and Ch.87 "Tablets, Capsules and Pills, pp 1655-1660, Mack Publishing Company, Easton, PA 1970.	
		Remington's Pharmaceutical Sciences, 17 th Ed., Ch 21, "Interfacial Phenomena" pp267-269, Mack Publishing Company, Easton, PA 1985.	
		Remington's Pharmaceutical Sciences, 18 th Edition, Ch 58, "Anagesics and Antipyretics" pp 1102, and Ch. 91, "Sustained-Release Drug Delivery Systems" pp 1676-1686, Mack Publishing Company, Easton, PA 1990.	
		Roff & Scott, Handbook of Common Polymers, CRC Press., Cleveland Ohio, 1971.	
		The Merck Index, 11 th Ed, p. 762, 1989.	
		The Physician's Desk Reference, 50 th Ed., pp. 1335-1337, 1996.	
		Lea & Febiger, The Pharmaceutical and Clinical Pharmacokinetics, 3 rd Ed., pp 1-28, 1984.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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